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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,981	01/13/2006	Cynthia C. Bamdad	13150-70090US	4121

7590 11/25/2008

Jhk Law
P.o. box 1078
La Canada, 91012-1078
CANADA

EXAMINER	
MCDOWELL, BRIAN E	
ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
11/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,981	BAMDAD, CYNTHIA C.	
	Examiner	Art Unit	
	BRIAN MCDOWELL	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/30/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/1/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

BEM

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group XV in the reply filed on 10/30/2008 is acknowledged. Claims 1-16 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely **traversed** the restriction (election) requirement in the reply filed on 10/30/2008. The traversal is on the ground(s) that there would be no serious search burden for the examiner and that the compounds and their use form a single invention concept. This is not found persuasive because the inventions were shown to lack a single inventive concept in the previous restriction requirement

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims drawn to an invention nonelected with traverse in the reply filed on 10/30/2008. A complete reply to this action must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

An action on the merits of claims 17-22 is presented herein.

Priority

This application receives the priority date of 9/14/2004, drawn to provisional application 60/610,038.

Information Disclosure Statement

The foreign and NPL documents cited on the IDS have not been considered since they were not provided by applicant.

Specification

The abstract of the disclosure is objected to because the cross-reference to related applications is incorrect. The instant application is not a continuation-in-part of application 09/996,069. The instant application is a national stage entry of PCT/US05/32821 and claims priority to provisional application 60/610038. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 17-22 are objected to because of the following informalities: The use of the abbreviations “MUC1, MGFR, MT1-MMP, and MMP-14”. The full name and not the abbreviations should be used within the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the instant claim 20, applicant recites the limitation “wherein the metal-dependent protein is an enzyme that cleaves MUC1".

There is insufficient antecedent basis for this limitation in the claim. Claims 21 and 22 depend on claim 20 and are therefore rejected.

Claim 17 recite the limitation “treating the patient with a compound comprising a MGFR binding region and metal chelator group”. The limitation “metal chelator group” is not described in the specification and it is not clear what functionalities are encompassed by this limitation. Therefore, the metes and bounds of the claim are not defined. Claims 18-22 depend on claim 17 and are rejected for indefiniteness.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated over Bamdad *et al.* (US 2003/0130293-mentioned by applicant in IDS).

Bamdad discloses a method for treating cancer characterized by aberrant expression of MUC1 using a variety of compounds that contain a quinazoline core (see abstract). The compounds interact with the MUC1 Growth Factor Receptor (MGFR), thus it must possess a MGFR binding region (see [0108]). Take for example the compound (see page 17, line 14), the "chelator group" may be the tertiary amine and the carbonyl group on any of the amide moieties present on the molecule that would serve to bind to metals such as zinc, magnesium or nickel. One of ordinary skill realizes that nitrogen and oxygen may act as Lewis bases and are readily capable of performing such tasks.

Also, since the compounds possess a MGFR binding region and a metal chelator group, it must inherently be capable of inhibiting a metal-dependent protein/enzyme (e.g., kinesins, matrix metalloproteases such as MT1-MMP or MMP-14) that cleave MUC1 (see [0127]).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of MUC1-positive cancers such as breast, lung, colon, and prostate; reasonably does not provide enablement for the treatment of the any other cancers that applicant is claiming. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant is not enabled for the **prevention** of any of the diseases covered by the scope as well.

Pursuant to In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is "undue"; see In re Vaeck, 20 USPQ2d 1438, 1444. Analysis is described below:

(A) Breadth of claims: Due to applicant's own definition of the word "cancer" in the specification:

The term "cancer", as used herein, may include but is not limited to: biliary tract cancer; bladder cancer; brain cancer including glioblastomas and medulloblastomas; breast cancer; cervical cancer; choriocarcinoma; colon cancer; endometrial cancer; esophageal cancer; gastric cancer; hematological neoplasms including acute lymphocytic and myelogenous leukemia; multiple myeloma; AIDS-associated leukemias and adult T-cell leukemia lymphoma; intraepithelial neoplasms including Bowen's disease and Paget's disease; liver cancer; lung cancer; lymphomas including Hodgkin's disease and lymphocytic lymphomas; neuroblastomas; oral cancer including squamous cell carcinoma; ovarian cancer including those arising from epithelial cells, stromal cells, germ cells and mesenchymal cells; pancreatic cancer; prostate cancer; rectal cancer; sarcomas including leiomyosarcoma, rhabdomyosarcoma, liposarcoma, fibrosarcoma, and osteosarcoma; skin cancer including melanoma, Kaposi's sarcoma, basocellular cancer, and squamous cell cancer; testicular cancer including germinal tumors such as seminoma, non-seminoma (teratomas, choriocarcinomas), stromal tumors, and germ

…etc., the scope of the claims is very large.

(B) The nature of the invention: Compounds for the treatment of cancer that are characterized by the MUC1 receptor.

(C) State of the Prior Art: Currently in the art, there are few quinazolinone compounds that can inhibit MUC1 as evident by the references on applicant's IDS.

(D) Skill of those in the art: The level of skill in the art is high.

The treatment of cancers has always been difficult since an effective dosage is not easy to establish. Even with the advanced training, a skilled oncologist would have to carry out extensive research to determine which of the claimed compounds is effective and safe. Such a task would require a tremendous amount of time, resource and effort.

(E) Level of predictability in the art: It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors

involved," and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(F) Direction or Guidance: The specification only describes assays involving breast, lung, colon, and prostate cancer using compounds (quinazolines) described in the specification. Thus, there is insufficient enablement to guide the skilled clinician to the treatment of other various forms of cancer characterized by MUC1 .

(G) Working Examples: The working examples provided by applicant in the specification are very limited.

(H) The quantity of experimentation needed: Since there are very limited working examples as described above, the amount of experimentation is expected to be high and burdensome.

Due to the level of unpredictability in the art, the very limited guidance provided, and the lack of working examples, the applicant has shown lack of enablement. MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BM

/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624